providing an electrosurgical generator;

coupling an output of the generator to tissue to be treated; and

A4 coupling electrosurgical energy from the generator into the tissue in an oscillatory manner until an impedance of the tissue rises to a value that indicates that the tissue is desiccated, wherein the electrosurgical energy is coupled into the tissue with an oscillatory frequency that lies within a thermal bandwidth of the tissue.

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~~20~~. A method as in claim ~~18~~, wherein the frequency is within a range of about one Hertz to about 20 Hertz.

Remarks

Claims 1-4 and 6-18 remain in the application. Claim 5 has been canceled and its provisions included in claim 6. Claim 19 and 20 are newly added.

Claims 12-16 were rejected under 35 U.S.C. 112, first paragraph, for undue breadth because the claims were drawn to a single means. Claims 12-16 have been amended to correct any undue breadth.

Claims 1-16 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. More specifically, claim 1 was rejected due to a lack of antecedent basis for the phrase "the controller" and claims 12-16 were rejected for failure to provide sufficient

structure to support the functions set forth. Claim 1 has been amended to correct the lack of antecedent basis and claims 12-16 have been amended to recite sufficient structure to support their included functions.

Claims 1-6, 8, 9 and 12-16 were rejected under 35 U.S.C. 102(e) as being anticipated by Miller, III (U.S. Patent 5,836,943, hereinafter referred to as the "Miller patent"). Of these claims, 1 and 12 are independent claims.

Applicants' claim 1, as amended, is directed toward an electrosurgical generator for desiccating tissue comprising a controller for cycling output power to cause a cycling of the tissue impedance, and a tissue impedance measurement circuit coupled to said controller for measuring impedance of the tissue. Claim 1 has been amended to clarify the operation of the controller where the controller cycles the output power by applying a predetermined amount of output power to the tissue, lowering the output power when the output voltage reaches a predetermined maximum, re-applying the predetermined amount of output power to the tissue if a measured tissue impedance does not indicate desiccation of the tissue, and terminating output power when the measured tissue impedance exceeds a predetermined value which indicates a desiccated condition of tissue.

Applicant's claim 12, as amended, is directed toward an electrosurgical generator for treating tissue by applying energy including a desiccation detector and a controller. The controller includes power control circuitry for repeatedly increasing and decreasing output power to the tissue to be treated. The power control circuitry is coupled to the desiccation detector and operates to adjust the output power in response to the degree of desiccation of the tissue. Claim 12 has been amended to clarify that this is accomplished by applying a predetermined amount of output power to the tissue, lowering the output power when an output voltage reaches a predetermined maximum, and re-applying the predetermined amount of output power to the tissue if the desiccation detector does not indicate desiccation of the tissue. Unlike claim 1, claim 12 does not include terminating the output power.

The Miller patent discloses an electrosurgical generator that includes an impedance measuring device and further discloses measuring a complex impedance of

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the tissue in between electrosurgical pulses or during electrosurgical pulses. The Miller patent describes the operation of the impedance measuring device and the electrosugical generator as follows:

> The controller 120 regulates the generator circuit 100 in response to the measure tissue complex impedance and the rate of change of impedance to provide improved electrosurgical effects. (col. 12, lines 59-61)
>
> The controller 120 analyzes the measured impedance and/or the rate of change of the measured impedance over a predetermined time period to determine the present condition of the tissue 11. The controller compares the present tissue condition with a desired surgical effect and regulates the generator circuit 110 to obtain the desired surgical effect. (col. 13, lines 5-10)
>
> The impedance measurement device 130 applies a predetermined frequency voltage across the tissue 11 that has a different frequency than the signals synthesized by the generator circuit 110 for electrosurgical effects. The impedance measurement device 130 measures the current through the tissue 11 at the predetermined frequency to determine the complex impedance of the tissue 11 and thereby the tissue condition. The controller 120 then regulates the generator circuit 110 in response to the measured tissue condition to obtain a desired surgical effect. (col. 13, lines 16-22)

In each case, the Miller patent simply states that the generator circuit is regulated in response to the measured tissue condition to provide a desired surgical effect. The Miller patent is not seen to teach or suggest anything more.

This is notably different from Applicant's invention, as recited in claim 1, which includes applying a predetermined amount of output power to the tissue, lowering the output power when the output voltage reaches a predetermined maximum, re-applying the predetermined amount of output power to the tissue if a measured tissue impedance does not indicate desiccation of the tissue, and terminating output power

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when the measured tissue impedance exceeds a predetermined value which indicates a desiccated condition of tissue.

This is also different from Applicant's invention as recited in claim 12, which also includes applying a predetermined amount of output power to the tissue and lowering the output power when the output voltage reaches a predetermined maximum. Applicant's claim 12 further includes re-applying the predetermined amount of output power to the tissue if a measured tissue desiccation does not indicate desiccation of the tissue.

The Examiner maintains that "depending on the measured impedance characteristics, the output power would be cycled at any necessary frequency which would inherently include very low frequencies." Applicant asserts that nowhere in Miller is found the ability to cycle output power as defined in Applicant's amended claims 1 and 12.

Because the Miller patent is not seen to teach or suggest an electrosurgical generator that operates to: 1) apply power; 2) lower the power when a voltage threshold is reached; and 3) reapply power if tissue desiccation is not indicated, Applicant submits that Applicant's claims 1 and 12 are not anticipated by the Miller patent.

Claims 2-4, 6-11 and 13-16 depend, either directly or indirectly from claims 1 or 12, and as such, are subject to the provisions of the claims from which they depend. Therefore, Applicant submits that these claims are also not anticipated by the Miller patent.

Claims 1-7, 8, 9, and 12-18 were rejected under 35 U.S.C. 102(e) as being anticipated by Yates (U.S. Patent 5,558,671, hereinafter known as the Yates patent). Of these claims, 1, 12, 17 and 18 are independent claims.

The Yates patent is directed toward an impedance monitoring device for measuring the impedance of tissue being treated with an electrosurgical device. The Yates patent discloses applying electrosurgery energy and detecting an impedance minimum Z_{min} that occurs as shown by the curve in figure 12. A function of the impedance minimum is used to predict an impedance at which coagulation occurs, Z_{target}

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and when that impedance is reached, electrosurgical energy is turned off. See for example, col. 5, lines 60-67, and col. 8, line 48 through col. 9, line 16.

However, this is clearly different from Applicant's invention as disclosed in claims 1 and 12 for the same reasons discussed above with respect to the Miller patent. In summary, the Yates patent is not seen to disclose an electrosurgical generator that 1) applies power; 2) lowers the power when a voltage threshold is reached; and 3) reapplies power if tissue desiccation is not indicated. In contradistinction, the Yates patent discloses applying electrosurgical energy, detecting an impedance minimum, calculating a coagulation impedance based on the impedance minimum, and continuing to apply energy until a coagulation impedance is reached or until a time out or error condition occurs.

Therefore, Applicant maintains that Applicant's claims 1 and 12 are not anticipated by the Yates patent.

Applicant's invention as recited in claim 17 is directed toward a method for applying energy to tissue, the method including the steps of a) applying a high current into a low impedance load until a maximum power is reached, b) adjusting the output voltage to maintain constant output power as impedance increases as tissue begins to desiccate, c) dropping the output power in response to a rapid rise in tissue impedance indicating the boiling of tissue, d) allowing the tissue impedance to fall to a predetermined minimum value and then raising the output power to cause an increase in tissue impedance, and, e) repeating steps b and c until impedance reaches a maximum value.

Applicant maintains that the Yates patent is clearly different from the invention set forth in claim 17. The Yates patent is not seen to disclose the steps of Applicant's claim 17, in particular steps c) dropping the output power in response to a rapid rise in tissue impedance indicating the boiling of tissue, d) allowing the tissue impedance to fall to a predetermined minimum value and then raising the output power to cause an increase in tissue impedance, and, e) repeating steps b and c until impedance reaches a maximum value.

The Yates patent may disclose determining an impedance minimum, but the

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minimum is not predetermined and furthermore is determined at the onset of the application of electrosurgical energy for the purpose of determining a coagulation impedance. This is sharp contrast to Applicant's claim 17 where, after application of current, the power is lowered and the tissue impedance is allowed to fall to a predetermined minimum before raising the power. In addition, these steps are repeated until the impedance reaches a maximum value.

At least for these reasons, the Yates patent is not seen to anticipate applicant's claim 17.

Applicant's claim 18 is also directed a method for applying energy to tissue. Claim 18 differs from claim 17 in that step c) involves dropping the output power if the output voltage exceeds a maximum value, and step d) includes raising the output power after a predetermined period of time to cause an increase in tissue impedance.

Applicant maintains that the Yates patent does not anticipate claim 18 for the same reasons as stated for Applicant's claim 17.

With regard to Yates generally, the Examiner maintains that "The measured tissue impedance is compared to a desired impedance range, and the output power is cycled accordingly." As stated above with respect to the Miller patent, Applicant asserts that nowhere in Yates is found the ability to cycle output power as defined in Applicant's amended claims 1, 12, 17, and 18.

The Examiner also asserts that "Yates also discloses a means to operate the system whereby the voltage and current are controlled to maintain a desired power profile to treat tissue (see column 9)." Applicant maintains that column 9 of the Yates patent discloses using the load impedance "to determine a preferred energy level, e.g. voltage, current or power level, based on a specific system load curve for a generator, instrument and/or application." However, regardless of the "load curve", the operations disclosed in the Yates patent still operate to simply apply electrosurgery energy, detect an impedance minimum Z_{min}, utilize a function of the impedance minimum to predict an impedance at which coagulation occurs, Z_{target} and to turn off the electrosurgical energy when that impedance is reached.

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Claims 2-4, 6-9, and 13-16 depend, either directly or indirectly from claims 1 or 12, and as such, are subject to the provisions of the claims from which they depend.

Therefore, at least for the reasons stated above, Applicant submits that claims 1-4, 6-9 and 12-18 are not anticipated by the Yates patent.

Claims 7, 17, and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Miller patent in view of the Yates patent.

Claim 7 depends from claim 1 and as such inherits the provisions of claim 1. Because claim 1 is not obvious over the Miller patent in view of the Yates patent, Applicant maintains that claim 7 is also not obvious over the same references.

Applicant further respectfully asserts that the references, either alone or in combination, fail to teach or suggest Applicant's invention as taught by claims 17 and 18.

The provisions of Applicant's claim 17 have been identified above, and Applicant maintains that neither the Miller patent, nor the Yates patent is seen to disclose the steps of Applicant's claim 17, in particular steps c) dropping the output power in response to a rapid rise in tissue impedance indicating the boiling of tissue, d) allowing the tissue impedance to fall to a predetermined minimum value and then raising the output power to cause an increase in tissue impedance, and, e) repeating steps b and c until impedance reaches a maximum value.

Also as mentioned above, claim 18 differs from claim 17 in that step c) involves dropping the output power if the output voltage exceeds a maximum value, and step d) includes raising the output power after a predetermined period of time to cause an increase in tissue impedance. Applicant maintains that that neither the Miller patent, nor the Yates patent is seen to disclose the steps of Applicant's claim 18, in particular steps c) and d) as described , and step e) repeating steps b and c until impedance reaches a maximum value.

At least for these reasons, Applicant maintains that claims 7, 17, and 18 are in fact patentable over the Miller patent in view of the Yates patent.

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Claims 19 and 20 have been newly added, and are also deemed to be patentable over the cited prior art. Support for the claim language can be found at least at page 5, lines 1-28. No new matter is added.

Double Patenting Rejection

A terminal disclaimer, in compliance with 37 C.F.R. 1.321(c) is submitted herewith to overcome the non-statutory double patenting rejection.

Consideration and allowance of the claims as amended is respectfully requested.

Respectfully submitted,

8/22/2000
Date

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